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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/848,600 | 05/03/2001 | Peter Watts | WC 111 | 9982 |

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AKIN GUMP STRAUSS HAUER & FELD L.L.P.
ONE COMMERCE SQUARE
2005 MARKET STREET, SUITE 2200
PHILADELPHIA, PA 19103-7013

EXAMINER

GAMBEL, PHILLIP

ART UNIT PAPER NUMBER

1644

DATE MAILED: 02/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/848,600 | WATTS ET AL. | |
| | Examiner | Art Unit | |
| | Phillip Gambel | 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment, filed 11/22/04, has been entered.
Claims 22, 29 and 35 have been amended.

Claims 20-36 are pending.

Claims 1-19 have been canceled previously.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.
This Action will be in response to applicant's amendment, filed 11/22/04.
The rejections of record can be found in the previous Office Action.
3. Upon reconsideration of applicant's direction to page 5, lines 3-4 of the instant specification with respect to the recitation of "plurality of microspheres", the previous objection to the specification has been withdrawn.
4. Upon reconsideration of applicant's arguments and amended claims, filed 11/22/04; the previous rejections rejected under 35 U.S.C. § 112, first paragraph, written description / new matter with respect to "about", "chemical or physical bonds" and the concentrations of ICAM-1 in microsphere formulations have been withdrawn.
5. Claims 20-36 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.
The specification as originally filed does not provide support for the invention as now claimed:
"which composition adheres to the epithelial and/or mucosal surface of the nasal cavity upon administration".

Applicant's arguments, filed 11/22/04, have been fully considered but are not found convincing essentially for the reasons of record.

Applicant argues that in the present situation, it is clear throughout the specification that the drug composition is intended to be administered intranasally and that one of the advantages of the composition is that it adheres to the interior of the nasal cavity (see page 3, lines 11-15 of the instant specification).

While applicant asserts that a person of ordinary skill in the art would have understood that the applicant was in possession of the "epithelial (cellular) surface" or to the "mucus overlying that surface", obviousness is not the standard for the addition of new limitations to the disclosure as filed.

It is noted that entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977).

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The specification as filed does not provide a sufficient written description for the recitation of "which composition adheres to the epithelial and/or mucosal surface of the nasal cavity upon administration" in the specification as filed. The specification does not provide sufficient blazemarks nor direction for the instant claims encompassing the above-mentioned "limitation", as currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above. See MPEP 714.02 and 2163.06

Applicant is invited to amend the claims to recite the limitations disclosed by the application as filed.

6. Claims 20-36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Igari et al. (U.S. Patent No. 5,482,706) (1449) AND/OR Greve et al. (U.S. Patent No. 5,589,453) (1449) in view of Wegner et al. (U.S. Patent No. 5,730,983) (1449), Gwaltney et al. (U.S. Patent No. 5,422,097) (1449), Illum (U.S. Patent No. 5,690,954) (1449), Illum (U.S. Patent No. 5,707,644) and Kublik et al. (Eur. J. Pharm. Biopharm. 39:192-196, 1993)(1449) essentially for the reasons of record.

Applicant's arguments, filed 11/22/04, have been fully considered but are not found convincing essentially for the reasons of record.

As applicant acknowledges, applicant's arguments and the examiner's rebuttal are essentially the same of record (e.g. see applicant's Response dated 2/5/04 and the previous Office Actions).

A more thorough review of applicant's arguments and the examiner's rebuttal of record can be found in the previous Office Actions.

With respect to applicant's assertion that Greve is a basic science reference in that no specific practical applications, pharmaceutical or otherwise are taught or suggested, applicant mischaracterizes the teachings of Greve on the preparation of human rhinovirus receptor (ICAM-1) compositions and their use to reduce human rhinovirus infectivity (see the entire document, including the Claims) and ignores that Greve is a U.S. Patent. In addition, applicant is reminded that U.S. Patents are presumed valid. See 35 USC 282.

While applicant asserts that there was no expectation of success of providing an anti-virally effect amount of ICAM-1 to the nasal cavity, it is noted that the arguments of counsel cannot take the place of evidence in the record. In re Schulze, 145 USPQ 716, 718 (CCPA 1965). See MPEP 716.01(C).

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Again, it is noted that once a prima facie case of obviousness has been made the burden of going further is shifted to applicant. In re Keller, 208 USPQ 871, 882 (CCPA 1981). This applicant has not done, but rather argues the references individually and not their combination. One cannot show non-obviousness by attacking references individually where the rejections are based on a combination of references. In re Young, 150 USPQ 725 (CCPA 1968). See MPEP 2145.

Again in response to applicant's arguments that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine 5 USPQ2d 1596 (Fed. Cir 1988) and In re Jones 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, the teachings of the references are clearly drawn to providing the HRV receptor or ICAM-1 to inhibit rhinovirus attachment and infectivity, including providing ICAM-1 to those areas susceptible to infection by rhinovirus (e.g. see Igari and Greve).

Again, as pointed out previously, the combination of references provide for appropriate pharmaceutical compositions comprising an active ingredient and

- teach the delivery of composition comprising ICAM-1 (e.g. column 5, line 4), chitosan, gelatin, microspheres, polymeric materials for nasal delivery (e.g. see Igari, see entire document, including Abstract, Summary of the Invention, Description of the Preferred Embodiments, columns 7-12, particularly columns 9-10);

- teach the use of the HRV receptor or ICAM-1 to inhibit rhinovirus attachment and infectivity, including providing ICAM-1 to those areas susceptible to infection by rhinovirus such as intranasal sprays (e.g. see Greve, see entire document, including Summary of the Invention, Description of the Preferred Embodiments, column 4, paragraph 2);

- teach delivering ICAM-1 derived antagonists, including controlled release preparations and polymeric materials (see Wegner, see entire document, including Detailed Description of the Preferred Embodiments, including administration or the Compositions of the Present Invention on columns 15-16);

- teach the use of antiviral ICMA-1 (column 10), including preparation of such antiviral agents for intranasal delivery (e.g. see Gwaltney, see entire document, particularly Description of the Preferred Embodiments, including columns 11-12, overlapping paragraph); and

- teach various bioadhesive formulations encompassed by the claims invention for drug deliver to the nasal cavity, as well as the various considerations of mixing said bioadhesives materials with a wide variety of active drugs to increase bioavailability upon administration (see entire documents of Illum '954, Illum '644 and Kublik et al.).

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One of ordinary skill in the art at the time the invention was made would have been motivated to provide ICAM-1 with a bioadhesive, including those encompassed by the claimed invention to increase bioavailability with a bioadhesive, including those encompassed by the claimed invention to increase the bioavailability of ICAM-1 in order to inhibit rhinovirus attachment and infectivity. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments have not been found persuasive.

7. No claim allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Phillip Gambel, PhD.
Primary Examiner
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February 18, 2005